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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,652	01/22/2005	Oleg Iliich Epshteni	0075.0011US1	8482

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
05/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/522,652	EPSHTENI ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-6* is/are pending in the application.

4a) Of the above claim(s) *4,5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/14/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 01/14/2008, has been entered.

Claim 3 has been canceled.

Claim 6 has been added.

Claims 1-2, 4-6 are pending.

Claims 4-5 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claims 1-2 and 6 are currently under examination as they read on a medicament comprising an anti-interferon alpha antibody in homeopathic dilution.

2. This Action will be in response to Applicant's Arguments/Remarks, filed 01/14/2008.

The rejections of record can be found in the previous Office Action.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 03/14/2008 was filed after the mailing date of the First Office Action on the Merits on 07/12/2007. The information disclosure statement is being considered by the examiner.

Specification

4. The disclosure is objected to because of the following informalities:

It appears that the word "centimal" on page 2 of the specification may have been a typo for "centesimal".

Appropriate correction is required.

Claim Objections

5. Claim 1 is objected to because of the following informalities: it appears that the last part of the claim is not grammatically correct. Applicant is invited amend the claim by replacing "being" with "are".

Claim Rejections - 35 USC § 112, second paragraph

6. The previous rejection under 35 USC 112 second paragraph has been withdrawn in view of Applicant's amendment, filed 01/14/2008.

Claim Rejections - 35 USC § 102

7. The previous rejection under 35 U.S.C. 102(e) as being anticipated by Chuntharapai et al. has been withdrawn in view of Applicant's amendment to the claims, filed 01/14/2008.

It is noted that Applicant stated in the argument that the newly added limitation *specifies that the potentiated form of antibodies to interferon prepared as homeopathic dilution do not **bind** and suppress the activity of the interferon* (page 6 of Remarks). However, it is noted that the amended claims do not recite any binding of the antibody to interferons.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chuntharapai et al. (U.S. Patent 7,087,726 B2) in view of Cavazza (U.S. Patent 5,683,712) and further evidenced by that potentization process which would inherently make the antibody non-suppressive to interferon as indicated by Applicant's Remarks, filed 01/14/2008, on pages 3-4.

In response to Applicant's first argument that the combined teachings of Chuntharapai and Cavazza does not meet the newly added limitation which specifies that the homeopathic dilutions of the potentiated forms of antibodies to interferon do not suppress the activity of the interferon, the following is noted.

As previously stated in the Office Action, mailed 07/12/2007, given that Chuntharapai teaches an anti-interferon antibody and that Cavazza teaches homeopathic technology is well-known in the art, it would have been obvious to one of ordinary skill in the art to make a medicament comprising the anti-interferon alpha antibody as taught by Chuntharapai in a homeopathic dilution to potentiate the antibody as taught by Cavazza (see column 1, lines 20-35). One of ordinary skill in the art would have been motivated to produce the medicament comprising the antibody in accordance with homeopathic technology because of the teaching by Chuntharapai et al. on using the anti-IFN-alpha antibody for treating autoimmune diseases (see column 6, lines 63-68) and the teaching by Cavazza that in order to induce the desired therapeutic effect, low doses of homeopathic remedy should be given (column 1, lines 15-20).

As such, the combined teachings of Chuntharapai and Cavazza necessarily meets the claim limitation for the following reason: the same or nearly the same antibody when homeopathically diluted to the "potentiated form", would no longer suppress interferon because the process of potentization would inherently make the potentiated form of the antibody no longer suppressive to interferon as evidenced by Applicant's own remarks stating that "concept of potentization as extreme dilution and that a remedy is prepared by extremely diluting the substance in a series of steps has been known and well defined in the US since at least the first half of the 19th century.

Homeopathy asserts that this process can maintain a substance's healing properties regardless of how many times it has been diluted… Potentiated diluted remedy is believed (without being committed to any specific scientific theory) to have modified properties of the solvent molecules or the clusters of the solvent molecules to cause therapeutic effect. While no definite scientific theory exists to explain how potentiated remedies work, it has been known that they work, along with the well known term "potentiated", defining such remedies."

Therefore, the composition comprising the anti-interferon alpha antibody, when subjected to extreme dilution, would have lost its inhibitory activity to the interferon as a definition of potentization process suggests.

Applicant's second argument is that the claimed products are not obvious due to commercial success, with applicant pointing to the declaration of inventor Oleg I. Epshtein to support this argument.

The argument of commercial success is not persuasive. First, evidence of commercial success must be commensurate in scope with the claims. The declaration discusses ultra-low dosages of antibodies to γ-interferon which appears to be in a single homeopathic dilution made using precise numbers and types of dilution steps. The instant claimed product is directed to antibody to interferon alpha in one or more generic homeopathic dilutions. As such, the species of one homeopathic dilution disclosed in the declaration does not support the claimed genus. Second, to be persuasive an argument of commercial success must show explicit sales results that demonstrate evidence of market share, including such things as total sales for competing products in the market, the differences between these competing products and applicant's product, total sales for products embodying the invention, pricing of the various products, information on advertising within relevant markets and any other information relevant to the inquiry. In other words, applicant must establish a nexus between the claimed features and the commercial success. As such, commercial success, if it exists, cannot be derived from other factors such as heavy promotion, advertising or brand name recognition. Note that gross sales figures do not show commercial success absent

evidence as to market share. See *Cable Electric Products, Inc. v. Genmark, Inc.* 770 F.2d 1025, 226 USPQ 881 (Fed. Cir. 1985). In the instant declaration, inventor Epshtein discloses that:

"Development of the medicaments based on ultra-low doses of antibodies has propelled Materia Medica, the inventor's company, to be one of the six largest manufacturers of medicines in Russia. Its Anaferon (the medicine based on ultra-low doses of antibodies to γ-interferon as described in the present application) Js in the top 20 best sellers on the Russian pharmaceutical market, with more than 760 million doses manufactured and sold. It is also one of the leading export products from Russia to Ukraine and Kazakhstan." (page 3 of declaration).

However, this data is irrelevant since the OTC market encompasses medicaments for all sorts of unrelated diseases and disorders, including such things as aspirin for headaches. What is needed is a comparison to other medicaments used to treat viral diseases. Further, how long has production been going on? How has it been determined that anti-interferon antibody is "a leading export product"? What is the relevance of any of this to the sales of other viral disease medicaments? In summary, it appears that the declaration of inventor Oleg I. Epshtein et al. fails to establish the required nexus between alleged commercial success and the instant claimed product.

Further, it should be noted that a strong case of obviousness may be established such that the objective evidence of nonobviousness is not sufficient to outweigh the evidence of obviousness. See MPEP 716.01(d).

The rejection is maintained.

Conclusion

10. No clam is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./
Examiner, Art Unit 1644
April 24, 2008

/Eileen B. O'Hara/
Supervisory Patent Examiner
Art Unit 1644